

## REMARKS

This is in response to the Official Action of May 3, 2004. The points raised therein are addressed below in the order originally set forth.

The present invention is explained in the instant application on page 2, lines 7-11, as follows:

In the course of studying certain endobiotic peptides described herein, it was unexpectedly discovered that these antimicrobial compounds were found in, or isolated from, mast cells. While mast cells are most often associated with allergic reactions, their precise role in host defense against disease is uncertain, and no peptide antibiotic has previously been isolated therefrom.

As discussed below, it is respectfully submitted that no prior art inconsistent with this assertion has been identified in the Official Action.

Claims 5-9 stand rejected as incomplete under 35 USC 112, second paragraph, for omitting allegedly essential steps on methods for detecting peptides having antimicrobial activity, and methods for isolating peptides. For the reasons set forth below, this rejection is respectfully traversed.

The manner by which antimicrobial activity can be determined is not critical. Any technique can be used. Determining antimicrobial activity of peptides is among the most well-established and routine techniques in microbiology, such that any additional specificity in the claims on this step would clearly undermine applicant's invention.

In addition, the manner by which peptides are isolated is not critical. Again, any technique can be used. The isolation of peptides is well established and numerous techniques are known to skilled workers. Again, any further specificity in the claims on this step would clearly undermine applicant's invention.

In discussing the issue of critical features allegedly not claimed, the *Manual of Patent Examining Procedure* notes as follows:

Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts.

....

Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

Accordingly, it is respectfully submitted that this rejection should be withdrawn.

Claim 9 stands rejected as indefinite as confusing, and this claim has been cancelled to simplify the issues.

Claims 5-6 and 8-9 stand rejected as anticipated under 35 USC 102(b) over Robinette et al. in light of Abraham. This rejection is respectfully traversed.

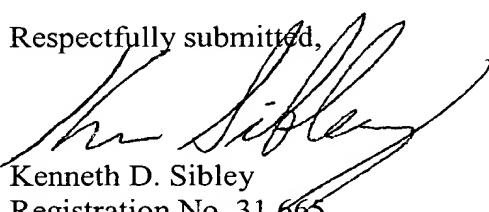
In the Official Action it is admitted that "Robinette et al. do not explicitly disclose the isolation of peptides from mast cells...." It is said, however, that mast cells are taught by Abraham et al. to be present in high concentrations in skin, and apparently alleged that Applicant respectfully disagrees. Robinette et al. is concerned with fish skin, while Abraham et al. is concerned with mammalian skin. It is well settled that the anatomy and physiology of mammalian skin is completely different, distinct, and non-analogous to that of fish skin: Mammals and fish diverging at the level of "class" on the phylogenetic tree; fish skin is relatively thin compared to mammals; fish skin secretes a an antifective mucous layer while mammalian skin does not; fish skin includes scales arising from the dermis while mammalian skin does not. Hence, skilled workers would not expect a finding with respect to mammalian skin to apply to fish skin. While Robinette describes antimicrobial peptides in fish skin (as acknowledged in the instant specification at Example 7), one would expect this activity to be associated with the mucous layer and associated secretory cells, and not with mast cells.

Further, the combination of references does not teach the step of "detecting a peptide having antimicrobial activity **in said mast cells**" because, prior to the instant application, the presence of antimicrobial compounds in mast cells was unknown.

Claims 5 and 7-9 stand rejected as obvious over Selsted et al. in view of Abraham. Selsted is said to describe isolating antimicrobial peptides from bovine neutrophils. It is acknowledged in the action that Selsted does not explicitly disclose the isolation of peptides from mast cells. However, it is alleged that, because of certain similarities between neutrophils and mast cells, skilled persons would expect the procedures for obtaining antimicrobial peptides taught in Selsted to be applicable to Abraham. Applicants respectfully disagree.

There is no showing or teaching in the references that procedures for isolating antimicrobial peptides from neutrophils would also be applicable to mast cells. In addition, while Abraham describes "microbicidal activities of mast cells" at page 3504, they do not disclose or teach microbicidal **peptides** from mast cells. Rather, Abraham discusses phagocytosis nonoxidative killing systems involving acidification of phagocytic vacuoles and the fusion of lysosomal granules, bactericidal acid hydrolases, oxidavite killing activity via the production of superoxide anions, singlet oxygen, hydroxyl radicals, and hydrogen peroxides, and "as yet uncharacterized microbicidal activities".

Respectfully submitted,

  
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